Patient profile and periprocedural outcomes of bioresorbable vascular scaffold implantation in comparison with drug-eluting and bare-metal stent implantation. Experience from ORPKI Polish National Registry 2014–2015

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Adv Interv Cardiol 2016; 12, 4 (46): 321–328
DOI: 10.5114/aic.2016.63632

Abstract

Introduction: There are limited data on the comparison of bioresorbable vascular scaffold (BVS) and drug-eluting stent (DES)/bare-metal stent (BMS) implantation in an unselected population of patients with coronary artery disease.

Aim: To compare the periprocedural outcomes and patient profile of BVS and DES/BMS implantation in an all-comer population from the ORPKI Polish National Registry.

Material and methods: A total of 141,324 consecutive patients from 151 invasive cardiology centers in Poland were included in this prospective registry between January 2014 and June 2015. Periprocedural data on patients with at least one BVS (Absorb, Abbott Vascular, Santa Clara, CA, USA), DES or BMS (all available types) implantation in de novo lesions during index percutaneous coronary intervention for stable angina (SA) or acute coronary syndrome were collected.

Results: Bioresorbable vascular scaffold was the most often used in patients with SA, in single-vessel disease and in younger male patients. Bioresorbable vascular scaffold implantation was significantly more often associated with periprocedural administration of ticagrelor/prasugrel (6.8% vs. 3.6%; $p = 0.001$) and use of intravascular ultrasound and optical coherence tomography in comparison with the DES/BMS group (2.8% vs. 0.6% and 1.8% vs. 0.1%, respectively; $p = 0.001$ for both). The incidence of periprocedural death was significantly lower in the BVS group than the DES/BMS group (0.04% vs. 0.32%; $p = 0.02$), but this difference was no longer significant after adjustment for covariates. On the other hand, coronary artery perforation occurred significantly more often during BVS delivery (0.31% vs. 0.12%; $p = 0.01$), and BVS implantation was identified as an independent predictor of coronary artery perforation in multivariate logistic regression analysis (OR = 6.728, 95% CI: 2.394–18.906; $p = 0.001$).

Conclusions: Patients treated with BVS implantation presented an acceptable safety and efficacy profile in comparison with the DES/BMS group. However, lower risk patients were the most frequent candidates for BVS implantation.

Key words: bioresorbable vascular scaffold, metallic platforms, all-comers, de novo lesions, stable angina, acute coronary syndrome, registries.

Introduction

Current guidelines recommend coronary stenting with new-generation drug-eluting stents (DES) for most indications of percutaneous coronary intervention (PCI) [1]. However, new-generation DES have not managed to address all the limitations of metallic stents [1]. These limitations may include caging of the vessel, impairment of vasomotion, chronic inflammation, late expansive remodeling, late thrombosis, potential preclusion of surgical revascularization and interference with magnetic resonance, imaging causing the blooming effect [2–6]. A bioresorbable vascular scaffold (BVS) ensures temporary vessel support with drug delivery to the endothelium without the potential long-term limitations of permanent metallic platforms [4, 5]. Results from the ABSORB trials have confirmed the safety and efficacy of BVS implantation in rather non-complex lesions [7]. However,

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Received: 16.08.2016, **accepted:** 6.11.2016.

there are still limited data on BVS versus metallic stent implantation in an unselected "real-world" population, both in terms of current use profile and periprocedural outcomes.

Aim

The aim of this study was to compare the periprocedural outcomes and patient profiles of BVS and DES/BMS implantation in an all-comer population from the ORPKI Polish National Registry.

Material and methods

All obtained data were stored in the electronic database of National PCI Registry (ORPKI) operated by the Jagiellonian University Medical College in Krakow. ORPKI is a national registry collecting data on all percutaneous procedures in interventional cardiology performed in Polish ORPKI is a national registry collecting data on all percutaneous procedures in interventional cardiology performed on Polish territory [8]. This registry is a single-arm prospective observational study. Between January 2014 and June 2015, it enrolled 141,324 consecutive patients from 151 invasive cardiology centers in Poland. Patients with at least one BVS (Absorb, Abbott Vascular, Santa Clara, CA, USA), DES or BMS (all available types) implantation in de novo lesions during index PCI for stable angina (SA) or acute coronary syndrome (ACS) were included. A flow chart of the patients is presented in Figure 1 A. All procedures were carried out according to current standards of PCI. No further evaluation or follow-up was performed after hospital discharge. The full range of sizes and lengths for both BVS and DES/BMS were available during the study period in all participating centers. The decision to implant a BVS rather than a DES/BMS was the operator's choice according to stent instructions. However, it was recommended for the purpose of this registry to qualify for Absorb BVS implantation according to a prespecified algorithm (Figure 1 B). Adverse events were diagnosed at the operator's discretion according to definitions in current ESC guidelines. The Independent Clinical Endpoint Committee was not involved in adverse events classification and validation of definitions. All patients provided informed consent for the procedure. The study complied with ethical principles for clinical research based on the Declaration of Helsinki with later amendments. No funding was used to support this registry.

Statistical analysis

Standard descriptive statistics were used in the analysis. Quantitative variables were described using mean ± standard deviation. Categorical variables were presented

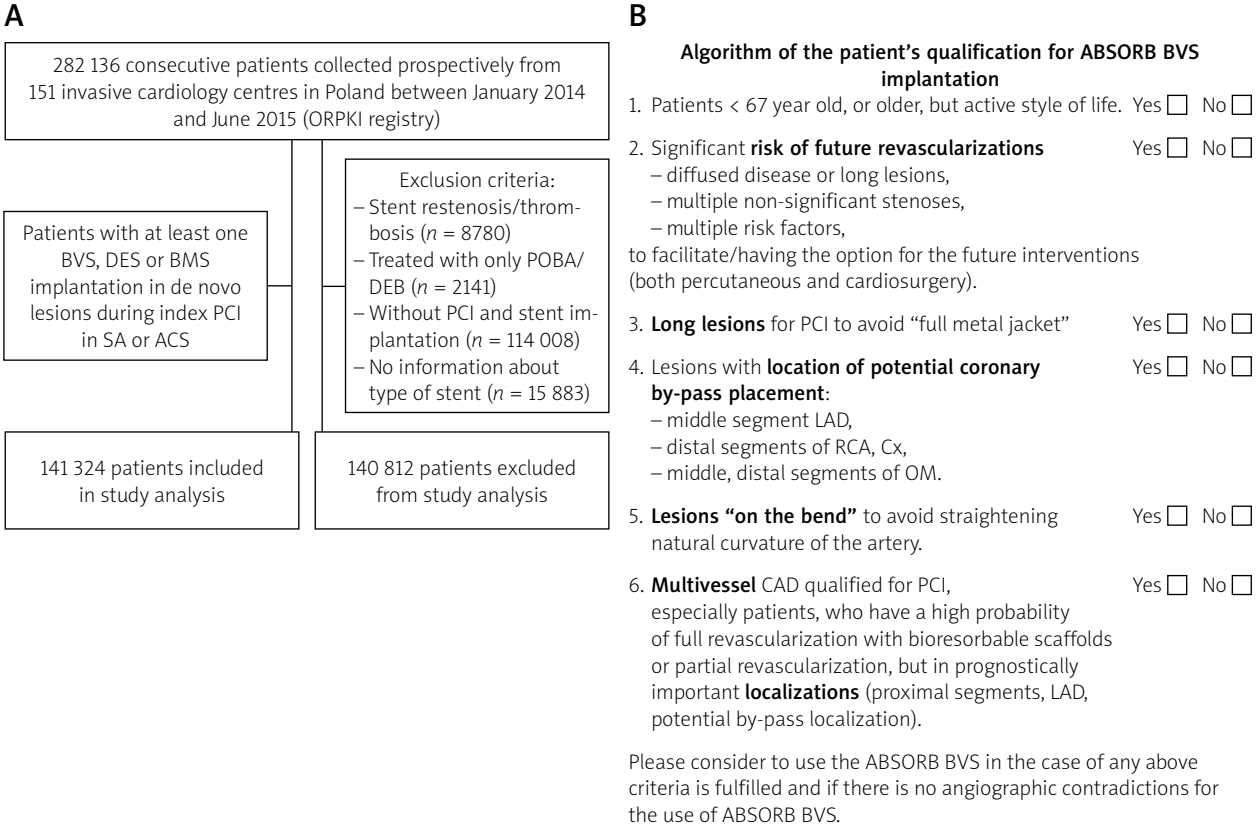

Figure 1. Flow chart of the patients (**A**) and algorithm of the patient's qualification for ABSORB BVS implantation (**B**)

Table I. Baseline patient characteristics

Parameter	BVS (*N* = 2,258)	DES and BMS (*N* = 139,066)	*P*-value
Male gender	1,597 (70.7%)	93,846 (67.5%)	0.001
Age [years]	59.97 ±10.6	66.79 ±10.8	0.001
Diabetes mellitus	437 (19.4%)	37,989 (27.3%)	0.001
Previous stroke	37 (1.6%)	4,666 (3.4%)	0.001
Previous MI	645 (28.6%)	39,802 (28.6%)	0.9
Previous CABG	75 (3.3%)	7,979 (5.7%)	0.001
Previous PCI	856 (37.9%)	45,119 (32.4%)	0.001
Smoking	517 (22.9%)	27,997 (20.1%)	0.002
Arterial hypertension	1,581 (70.0%)	100,494 (72.3%)	0.02
CKD	50 (2.2%)	7311 (5.3%)	0.001

BMS – bare metal stent, BVS – bioresorbable vascular scaffold, CABG – coronary artery bypass grafting, CKD – chronic kidney disease, DES – drug-eluting stent, MI – myocardial infarction, PCI – percutaneous coronary intervention.

as counts and percentages. The level of statistical significance was set at $p < 0.05$. The Mann-Whitney *U* test (for non-normal distribution of data) or unpaired (two-sample) Student's *t*-test (for normally distributed data) was applied for continuous variables. The χ^2 test was used for categorical (nominal and dichotomous) variables. In addition, multivariate logistic regression analysis was performed to find independent predictors of periprocedural death and perforation of the coronary artery. Forward selection in logistic regression analysis with a probability value for covariates to enter the model was set at the 0.05 level. All baseline and procedural characteristics were tested. Results were presented as odds ratios (OR) with 95% confidence intervals (CI). All analyses were carried out with Statistica 10 (StatSoft, Inc. Tulsa, OK, USA).

Results

Scaffold implantation was performed in 2,258 patients. Metallic stents were used in 139,066 procedures. Bioresorbable vascular scaffold was more often used in patients with SA, in single-vessel disease and in younger male patients (Tables I and II). Diabetes mellitus, arterial hypertension, previous stroke, chronic kidney disease and previous coronary artery bypass grafting were significantly less frequently reported in patients with BVS implantation as compared to the DES/BMS group. Incidence of BVS delivery to the left anterior descending (LAD) coronary artery was significantly higher as compared to the DES/BMS group (54.3% vs. 35.9%; $p = 0.001$). The right radial access was the most common during PCI, with a higher rate of its use in BVS patients as compared to DES/BMS patients (62.5% vs. 50.2%; $p = 0.001$). Overall, 165,188 metallic stents were implanted in the DES/BMS group (145,472 (88.1%) DES; 19,716 (11.9%) BMS; 3,355 (2%) DES and BMS simultaneously in one patient) and 2,407 biodegradable scaffolds in the BVS group. No differences were found between groups in terms of mean number of deployed stents per patient (BVS vs. DES/BMS: 1.07 ±0.3 vs. 1.09 ±0.6; $p = 0.9$). Most often one scaffold was implanted in the BVS group (94%), two were delivered in 5.5%, three in 0.4% and four in 0.4% of all cases. Data describing the number of delivered scaffolds or stents to particular vessels are presented in Table III. No BVS implantation was reported in 48 (31.8%) participating centers. Experience with 1–10 devices was noted in 63 (41.7%), 10–50 were used in 29 (19.2%) and 50–100 scaffolds were deployed in 5 (3.3%)

Table II. Indications for percutaneous coronary intervention ($p = 0.001$ for all comparisons)

Parameter	BVS (*N* = 2,247)	DES and BMS (*N* = 138,440)
SA	1,169 (52)	49,581 (35.8)
UA	562 (25)	35,384 (25.6)
STEMI	256 (11.4)	29,662 (21.4)
NSTEMI	260 (11.6)	23,813 (17.2)
CTO	54 (2.4)	431 (0.3)
Bifurcation	72 (3.2)	7840 (5.7)
	BVS (*N* = 1,715)	**DES and BMS (*N* = 114,356)**
Single-vessel disease	1,150 (67.1)	54,882 (48.0)
LMCA	6 (0.4)	137 (0.1)
Multi-vessel disease without LMCA	530 (30.8)	53,678 (47.0)
Multi-vessel disease with LMCA	29 (1.7)	5,659 (4.9)

BMS – bare metal stent, BVS – bioresorbable vascular scaffold, CTO – chronic total occlusion, DES – drug-eluting stent, LMCA – left main coronary artery, NSTEMI – non-ST-segment elevation myocardial infarction, SA – stable angina, STEMI – ST-segment elevation myocardial infarction, UA – unstable angina.

Table III. Number of scaffolds or stents implanted in particular vessels

Parameter	BVS (*N* = 2,407) *n* (%)	BMS (*N* = 19,716)	DES (*N* = 145,472)	*P*-value
LMCA	15 (0.6)	251 (1.2)	3,652 (2.5)	0.001
LAD	1,306 (54.3)	4,726 (24.0)	54,630 (37.6)	0.001
Cx	538 (22.4)	5,065 (25.8)	36,970 (25.4)	0.001
RCA	538 (22.4)	9,497 (48.2)	48,369 (33.3)	0.001
LIMA/RIMA	2 (0.1)	18 (0.1)	295 (0.2)	0.001
SvG	8 (0.3)	159 (0.8)	1,556 (1.1)	0.001

BMS – bare metal stent, BVS – bioresorbable vascular scaffold, Cx – circumflex, DES – drug-eluting stent, LAD – left anterior descending, LIMA/RIMA – left/right internal mammary artery, SvG – saphenous vein grafts, RCA – right coronary artery.

participating catheterization laboratories. Over 100 BVS were delivered in only 6 (4.0%) highly experienced invasive cardiology centers. The highest volume was represented by a catheterization laboratory with implantation of 190 scaffolds. A higher number of BVS utilization was noted in 2015 in comparison with corresponding months of 2014. The lowest scaffold deployment was reported during July-August and at the end of 2014. The mean number of implanted scaffolds was 21.9 ±183.9 per catheterization laboratories with experience in BVS utilization. Periprocedural therapy used during PCI is shown in Table IV. Thrombolysis in Myocardial Infarction flow before and after PCI is demonstrated in Figure 2. Bioresorbable vascular scaffold implantation was significantly

Table IV. Percutaneous coronary intervention details

Parameter	BVS (*N* = 2,258)	DES and BMS (*N* = 139,066)	*P*-value
Radiation dose [mGy]	1,144.6 ±852.2	1,171.4 ±1,008.6	0.02
Contrast volume [ml]	169.2 ±69.7	178.4 ±77.6	0.001
IVUS	63 (2.8%)	817 (0.6%)	0.001
OCT	40 (1.8%)	132 (0.1%)	0.001
Rotablation	5 (0.2%)	610 (0.4%)	0.1
Aspiration thrombectomy	65 (2.9%)	5,991 (4.3%)	0.001
Aspiration thrombectomy in STEMI patients	42 (16.4%)	5,115 (16.4%)	1.0
Antiplatelet and antithrombotic therapy:			
ASA administered during PCI	647 (28.7%)	45,095 (32.4%)	0.001
$P2Y_{12}$ inhibitors before and during PCI	2,258	139,066	0.001
Clopidogrel	2,106 (93.2%)	134,124 (96.4%)	0.001
Ticagrelor	99 (4.4%)	3,899 (2.8%)	0.001
Prasugrel	53 (2.4%)	1,043 (0.8%)	0.001
GP IIb/IIIa inhibitors	11 (0.5%)	413 (0.3%)	0.1
Abciximab	2 (18.2%)	142 (34.4%)	0.1
Eptifibatide	9 (91.8%)	257 (62.2%)	0.1
Tirofiban	0 (0.0%)	14 (3.4%)	0.1
UFH	2,034 (90.1%)	118,440 (85.2%)	0.001
Bivalirudin	8 (0.4%)	1,041 (0.8%)	0.03
LMWHs	79 (3.5%)	5,476 (3.9%)	0.3

ASA – acetylsalicylic acid, BMS – bare metal stent, BVS – bioresorbable vascular scaffold, DES – drug-eluting stent, FFR – fractional flow reserve, IVUS – intravascular ultrasound, LMWHs – low-molecular-weight heparins, OCT – optical coherence tomography, UFH – unfractionated heparin, GP – glycoprotein.

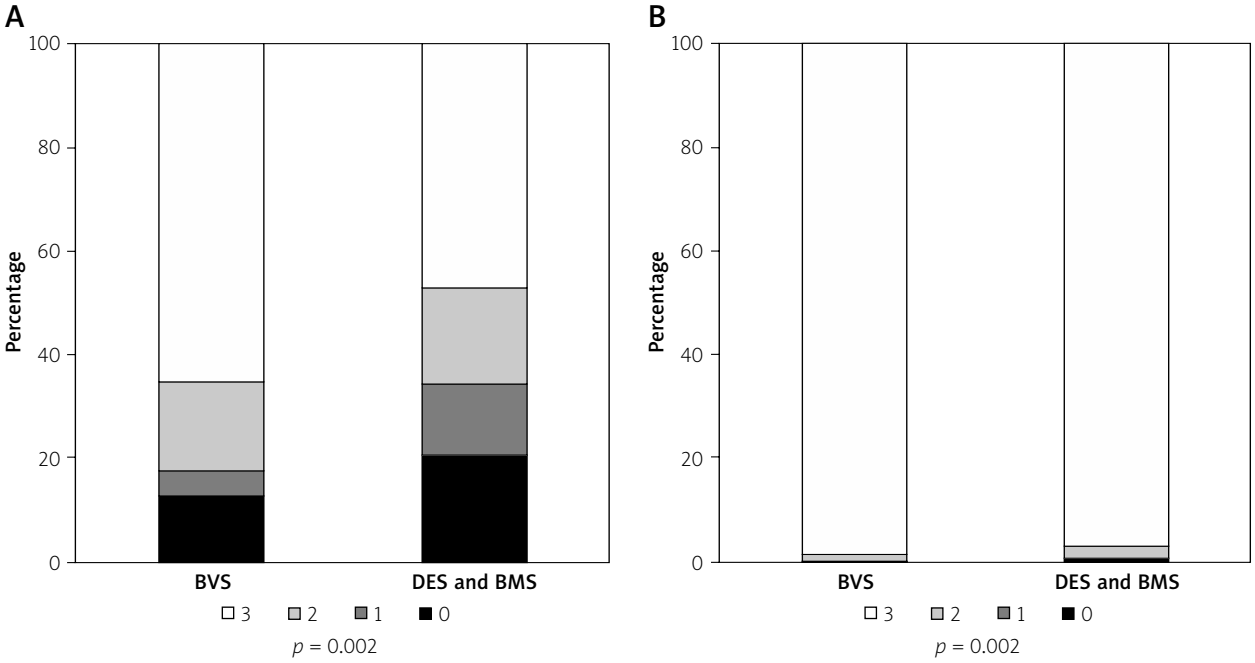

Figure 2. Thrombolysis in myocardial infarction before (**A**) and after (**B**) percutaneous coronary intervention

more frequently associated with periprocedural administration of ticagrelor/prasugrel (6.8% vs. 3.6%; $p = 0.001$) and use of intravascular ultrasound (IVUS) and optical coherence tomography (OCT) in comparison with the DES/BMS group (2.8% vs. 0.6% and 1.8% vs. 0.1%, respectively; $p = 0.001$ for both). There were no differences between the BVS group and the DES/BMS group in terms of incidence of periprocedural events such as myocardial infarction (0.0% vs. 0.1%; $p = 0.1$), no-reflow (0.35% vs. 0.45%; $p = 0.5$), vascular access site bleeding (0.09% vs. 0.12%; $p = 0.7$), sudden cardiac arrest (0.2% vs. 0.4%; $p = 0.2$) or allergic reactions (0.09% vs. 0.15%; $p = 0.4$). Higher incidence of perforation of coronary artery was reported in the BVS group (0.31% vs. 0.12%; $p = 0.01$), but periprocedural death occurred less frequently in patients treated with BVS (0.04% vs. 0.32%; $p = 0.02$). In the logistic regression analysis age (OR = 1.028, 95% CI: 1.006–1.05; $p = 0.01$) and BVS implantation (OR = 6.728, 95% CI: 2.394–18.906; $p = 0.001$) were identified as independent predictors of perforation of the coronary artery. On the other hand, male gender (OR = 0.525, 95% CI: 0.326–0.847; $p = 0.008$) and TIMI class before PCI (OR = 0.784 per 1 class increase, 95% CI: 0.65–0.945; $p = 0.01$) were considered to decrease the risk of this adverse event. No significant impact of rotablation was found (OR = 7.201, 95% CI: 0.968–53.562; $p = 0.054$). Male gender (OR = 7.502, 95% CI: 2.045–27.523; $p = 0.002$), age (OR = 1.024, 95% CI: 1.01–1.039; $p = 0.001$), diabetes mellitus (OR = 1.609, 95% CI: 1.13–2.291; $p = 0.008$), cardiogenic shock at admission to the catheterization laboratory (OR = 33.689, 95% CI: 24.366–46.579; $p = 0.001$), previous stroke (OR = 1.834, 95% CI: 1.072–3.138; $p = 0.03$) and myocardial infarction in past medical history (OR = 2.395, 95% CI: 1.587–3.614; $p = 0.001$) were significant predictors of periprocedural death. Arterial hypertension (OR = 0.561, 95% CI: 0.402–0.782; $p = 0.001$) and TIMI class before PCI (OR = 0.547 per 1 class increase, 95% CI: 0.468–0.639; $p = 0.001$) correlated negatively with the risk of mortality during PCI.

Discussion

Patients with a lower risk profile were the most frequent candidates for BVS implantation. The presented results are consistent with the main criteria of the algorithm used for patient's qualification for Absorb BVS implantation (Figure 1 B). To our best knowledge, this registry is to date the largest multicentre report of everyday usage of BVS in "real-world" settings. Indications for PCI with BVS were comparable to those reported in the GHOST-EU registry [9]. However, our registry included less ST-elevated myocardial infarction(STEMI)/non ST-elevated myocardial infarction (NSTEMI) in favor of patients with unstable angina. The safety and efficacy of BVS implantation with very good procedure results in both ACS and SA have been presented in several studies [9–13]. In our registry treatment of lesions in the middle and distal portion of the LAD was seen as a particularly strong indication for use of BVS over a metallic stent in order to reduce limitation in future PCI or bypass grafting by left internal mammary artery utilization. As previously suggested, younger patients were considered to have the greatest theoretical benefit over a permanent stent in cumulative reduction of the risk of late scaffold thrombosis (ScT) [13]. A similar observation regarding selection of patients and lesions for BVS implantation has been presented in a few large studies [2, 9]. Patient selection for

BVS implantation in this registry was consistent with the main criteria of recommendations from both a European and a Netherlands consensus [14, 15], which indicate the highest beneficial effect on longtime clinical outcome after scaffold deployment. Procedural success depends not only on proper selection of patients but also lesions [16]. Several studies have suggested benefit from intracoronary imaging with IVUS and/or OCT for optimization of PCI results [17]. However, according to the European consensus it is not routinely recommended for this purpose [15]. Intravascular ultrasound is used for the evaluation of the plaque morphology and in the preparation phase. Optical coherence tomography allows better optimization of scaffold deployment. In addition, it could be more useful in complex lesions or bifurcations [18]. Several studies have presented high variability in intravascular imaging utilization during PCI with BVS deployment [9, 19–21]. Our registry showed lower frequency of OCT and IVUS utilization in comparison with most of the above-mentioned studies. However, rates of imaging use were similar to those reported in the previous Polish national registry of BVS implantation [2]. Vessel visualization with these procedures was not mandatory, but it was performed in difficult cases with a questionable result of scaffold deployment. According to the European consensus, the new users of BVS should have a lower threshold for the use of imaging before and after BVS implantation [15]. Increased risk of ScT and myocardial infarction were early concerns raised with introduction of BVS utilization. The GHOST-EU registry presented cumulative incidence of definite/probable ScT of 1.5% at 30 days and 2.1% at 6 months (most of the cases occurred during 30 days after PCI) [9]. Further analysis revealed that 20 of 23 patients with ScT were on dual antiplatelet therapy (DAPT) at the time of thrombosis [22]. Early events were mostly attributable to procedural issues (i.e., dissection, incomplete scaffold apposition or expansion), and late events are more likely linked to scaffold-related factors and vascular responses [22]. The ScT rate after BVS delivery was also higher than for metallic stents in other "real-world" registries (3.0% in the AMC registry [23], 1.3% in the Registro Absorb Italiano registry [24] – preliminary data). However, the rate of ScT was not higher in the largest, most recent randomized controlled clinical trial [25]. Higher prevalence of thrombosis was reported in the first 30 days after implantation, similar to the frequency distribution for metallic stents [22]. To reduce the ScT rate, thorough selection of lesions and PCI techniques, more aggressive plaque modification before BVS implantation, routine high-pressure non-compliant balloon post-dilatation to ensure adequate scaffold expansion and more frequent use of intravascular imaging to optimize lesion coverage and scaffold dimensions was recommended [22, 26]. On the other hand, extensive and time-consuming lesion preparation might lead to periprocedural myocardial infarction, coronary dissection or even vessel perforation [17]. In this registry incidence of perforation of coronary artery during BVS delivery was significantly higher in comparison with the metallic stent group. In the previous Polish national registry dissection occurred in 2.9% of all cases [2]. Another study demonstrated perforation of coronary arteries in 0.73% of included patients [27]. The results of our logistic regression analysis may support the idea of a possible impact of extensive lesion preparation before BVS implantation on increased risk of coronary artery perforation. In our study patients with a lower risk profile were the most frequent candidates for BVS implantation, which might be the reason for significantly lower periprocedural mortality in this group. This positive impact of BVS on periprocedural mortality was no longer significant after adjustment for covariates. Importantly, cardiogenic shock at admission to the catheterization laboratory was the strongest predictor of periprocedural death. A recent meta-analysis reported periprocedural myocardial infarction (according to the Society of Cardiac Angiography and Interventions criteria) in 0.8% of patients with BVS implantation [26]. In our study no periprocedural myocardial infarction was reported in the BVS group. The incidence of MI was low, probably due to inclusion of periprocedural events only. In a recent meta-analysis [28] patients treated with BVS implantation had a similar risk of myocardial infarction (OR = 1.36, 95% CI: 0.98–1.89; $p = 0.06$) and death (OR = 0.95, 95% CI: 0.45–2.00; $p = 0.89$) but with higher risk of define/probable ScT (OR = 1.99, 95% CI: 1.00–3.98; $p = 0.05$), especially between 1 and 30 days after implantation (OR = 3.11, 95% CI: 1.24–7.82; $p = 0.02$) as compared to the metallic stent group [28]. However, Cassese *et al.* did not evaluate target vessel myocardial infarction (TVMI), which was significantly higher for BVS in comparison to conventional stents in data presented in two other meta-analyses [26, 29, 30]. Also, Cassese *et al.* did not discuss the numerically higher (but not statistically significant) prevalence of any-cause myocardial infarction in BVS patients (5.2% vs. 3.5%; $p = 0.06$). Lipinski *et al.* also reported that patients who received a BVS were at a higher risk of myocardial infarction (OR = 2.06, 95% CI: 1.31–3.22, $p = 0.002$) and definite/probable ScT (OR = 2.06, 95% CI: 1.07–3.98, $p = 0.03$) compared with the metallic stent group, whereas there was a lower (but not at the level of statistical significance) all-cause mortality with a BVS (OR = 0.40, 95% CI: 0.15–1.06, $p = 0.06$) [31]. This meta-analysis was limited by methodology that mixed SA and STEMI, single-arm registries and randomized trials, and included unpublished, non-peer reviewed registries [22, 30]. In a recent patient-level, pooled meta-analysis of four randomized studies, TVMI was increased with BVS compared with DES (OR = 1.45, 95% CI: 1.02–2.07; $p = 0.04$), due in part to non-significant increases in periprocedural myocardial infarction and device thrombosis with BVS (OR = 2.09, 95% CI: 0.92–4.75, $p = 0.08$) [26]. The relative rates of all-cause and cardiac

mortality and all-cause myocardial infarction did not differ between BVS and metallic stents [26]. Also data from the meta-analysis by Banach *et al.* were not able to detect statistically significant differences in 1-year outcomes between BVS and metallic stents [30]. The results showed significantly increased risk of TVMI between BVS and conventional stents (OR = 1.45, 95% CI: 1.03–2.05; p = 0.03) [29]. No other significant differences between BVS and conventional stents were reported except any-cause myocardial infarction (OR = 1.36, 95% CI: 1.00–1.85, p = 0.049) [29]. Furthermore, BVS might provide intrinsically less kinetic support than metallic stents, especially 6 to 12 months after implantation when the radial strength is diminished as a consequence of resorption kinetics [31]. This might be responsible for the numerically higher risk of any-cause myocardial infarction with BVS versus metallic stents implantation and the significant increase of TVMI reported in a few meta-analyses. Furthermore, BVS might entrap more thrombotic content between the vessel and the scaffold, because of the larger wall surface coverage and the greater strut thickness than the current thin-strut DES [29]. On the other hand, it might lead to an increased incidence of ScT after BVS implantation. Administration of proper antiplatelet drugs seems to be crucial for optimal clinical results and a low rate of ScT after BVS implantation [29]. In a large "real-world" registry antiplatelet therapy was prescribed at discharge in all patients and recommended for at least 12 months in 93.6% of them [9]. Clopidogrel, prasugrel and ticagrelor were prescribed in 73.2%, 26.2% and 0.6% of patients, respectively [9]. A recent patient-level, pooled meta-analysis presented prasugrel or ticagrelor utilization in 24% of patients with BVS implantation [26]. A lower rate of newer antiplatelet drug administration during the procedure was reported in our registry in comparison with above-mentioned studies; however, newer antiplatelet agents were significantly more often administered in BVS implantation in comparison with DES/BMS. This result is in line with current recommendations for antiplatelet therapy after BVS implantation [14, 15]. The present data might also be considered as a marker of preferences of BVS and antiplatelet therapy utilization in particular invasive cardiology centers in Poland.

The main limitation of this prospective observational study is its non-randomized design and all the known drawbacks of single-arm registry studies. The analysis included all available types of DES and BMS. Comparison with new-generation DES may be more appropriate to evaluate the safety and efficacy of BVS implantation. The possibility of the results being affected by unknown confounding factors cannot be excluded. There is a potential bias caused by the lack of in-hospital and long-term follow-up data in terms of clinical endpoints. There is a lack of angiographic data describing lesion type and morphology. Detailed data on device types and sizes were also not provided in the ORPKI registry.

The relatively small sample size of patients with BVS implantation and low incidence of adverse events suggest that our study should be considered exploratory and hypothesis generating.

Conclusions

Patients treated with BVS implantation presented an acceptable safety and efficacy profile in comparison with the DES/BMS group. Lower risk patients were the most frequent candidates for BVS implantation. Scaffold implantation might be associated with higher risk of coronary artery perforation. Periprocedural administration of ticagrelor/prasugrel and use of intravascular imaging were significantly higher in the BVS group in comparison with DES/BMS.

Conflict of interest

The authors declare no conflict of interest.

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